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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,883	11/20/2001	Roberto A. Macina	DEX-0271	3398

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EXAMINER	
HORLICK, KENNETH R	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

ICD

Office Action Summary	Application No.	Applicant(s)	
	10/001,883	MACINA ET AL.	
	Examiner	Art Unit	
	Kenneth R Horlick	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6,10-14,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8. (2 pages)
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: SEQUENCE ANALYSIS (3 pages)

1. Applicant's election with traverse of Group I, claims 1-5, 7-9, and 15, and SEQ ID NO:66 in the response filed 10/21/03 is acknowledged. The traversal is on the grounds that there is no serious search burden to search all of the groups. This is not found persuasive for the following reasons. First applicants do not address the independence and distinctness of each of the Groups as outlined in the requirement for restriction mailed 09/22/03. Second, the searches are not coextensive as applicants assert. A complete search of the method claims requires more than a search of the sequences, but also includes a search of the methods themselves. Further, there is no right to the search of 10 unrelated sequences in one application.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 6, 10-14, 16, 17, and nucleic acid sequences other than SEQ ID NO:66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed 10/21/03.

3. The disclosure is objected to because of the following informalities: the disclosure contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP j 608.01. Embedded hyperlinks and/or other form of browser-executable code appear in at least the following locations: pages 54, 60, and 61.

4. Claims 1-5, 7-9, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) These claims are vague and indefinite because they claim more than was elected.

B) The recitation of "selectively hybridizes" (claim 1) is vague, indefinite, and incomplete because the term is a relative one and no frame of reference is given. The determination or characterization of selective hybridization requires knowledge or disclosure of other potential hybridization targets and/or probes in the reaction mixture. None is given or mentioned; thus the claim is vague, indefinite, and incomplete.

C) The recitation of "means for determining the presence of the nucleic acid molecule of claim 1" (claim 15) is vague and indefinite because such means are not clearly defined. While this claim appears to invoke "means plus function" language according to 35 U.S.C. 112, 6th paragraph, it cannot be determined from the specification what means are contemplated. Clarification is required.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-9, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Firstly, this rejection applies to the claims insofar as the embodiments in claim 1 of (c) and (d); that is, nucleic acids which selectively hybridize to SEQ ID NO:66, or those having at least 60% sequence identity to said sequence. Although the specification only discloses the sequence of SEQ ID NO:66, these embodiments cover a large genus of related nucleic acids which are not described and were not in applicant's possession. Included in this genus are any number of nucleic acids which have some sequence homology with SEQ ID NO:66, but nonetheless have substantially different and unpredictable properties, such as encoding a polypeptide of substantially or completely different biological function. Thus, the specification does not have written descriptive support for the large genus as set forth in parts (c) and (d) of claim 1.

Secondly, this rejection applies in another manner with respect to claim 3, which requires genomic DNA. The specification fails to describe the complete genomic DNA sequence corresponding to the cDNA sequence of SEQ ID NO:66. Thus, applicants were clearly not in possession of the subject matter as claimed in claim 3.

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5, 7-9, and 15 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The instant application does not disclose a specific, substantial, and credible utility for the nucleic acid sequence mentioned in the claims. The instant application does not disclose a connection between presence or expression of SEQ ID NO:66 and colon cancer. For example, none of the tables on pages 116-124 shows such a nexus. The demonstration of expression of a sequence in a specific tissue type cannot be translated to mean that that sequence is necessarily a marker for cancer in that tissue. In addition, the application does not disclose or teach the meaning or significance of any particular assay for expression of SEQ ID NO:66. Thus, the instant application does not disclose a specific, substantial, and credible utility for SEQ ID NO:66, nor is there a readily apparent utility under 35 U.S.C. 101 for SEQ ID NO:66.

Claims 1-5, 7-9, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The discussion in the rejection under 35 U.S.C. 101 is incorporated here.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Dolganov (US 5,821,091).

These claims are drawn to an isolated nucleic acid molecule which comprises SEQ ID NO:66, or a nucleic acid that selectively hybridizes to SEQ ID NO:66, or a nucleic acid having at least 60% sequence identity to SEQ ID NO:66.

Dolganov discloses the cloning of a cDNA (SEQ ID NO:114) which has a region of about 82% identity with instant SEQ ID NO:66 across a portion of about 8% of SEQ ID NO:66 (see columns 151-154, and also attached page of sequence analysis and comparison done by the PTO). The nucleic acid taught by Dolganov cannot be distinguished from that being claimed in claim 1, as the noted sequence (due to the noted region of high homology): i) would be expected to "selectively hybridize" to instant SEQ ID NO:66; and ii) has at least 60% sequence identity to SEQ ID NO:66. The Dolganov sequence is a cDNA (claim 2) and is human (claims 4 and 5), and this reference further teaches a vector comprising said cDNA, a host cell comprising said vector, and expression of encoded protein using said host cell.

8. Claims 1, 3, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by human EST Accession No. AQ016709, available to the public on June 09, 1998.

These claims are drawn to an isolated nucleic acid molecule which comprises SEQ ID NO:66, or a nucleic acid that selectively hybridizes to SEQ ID NO:66, or a nucleic acid having at least 60% sequence identity to SEQ ID NO:66.

EST Accession No. AQ016709 discloses a DNA which has a region of about 84% identity with instant SEQ ID NO:66 across a portion of about 13% of SEQ ID NO:66 (see two pages of attached sequence analysis and comparison done by the PTO). The nucleic acid of this EST cannot be distinguished from that being claimed in claim 1, as the noted sequence (due to the noted region of high homology): i) would be expected to "selectively hybridize" to instant SEQ ID NO:66; and ii) has at least 60% sequence identity to SEQ ID NO:66. The EST Accession No. AQ016709 sequence is a genomic DNA (claim 3) and is human (claims 4 and 5).

9. It is noted that SEQ ID NO:66 is free of the prior art, as no prior art has been found teaching or suggesting this exact sequence.

10. No claims are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905 (571-272-0784 in Jan. 04). The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kenneth R. Horlick, Ph. D.

Kenneth R Horlick
Primary Examiner
Art Unit 1637

12/03/03